17 TECHNICAL PROCEDURES AND MANUALS

17.1 Principle

Any examination performed at the Department must be done in a manner that is, first and foremost, scientifically defensible. A critical part of the system for ensuring this defensibility is the documentation of the procedures used for examinations in each Section's Technical Procedures Manual. Format of Technical Procedures Manuals is discussed in Section 4 of this manual.

17.2 Procedures

17.2.1 Procedures used in each Section must be documented as generally accepted by that Section's peers in the forensic community. Procedures that are not so documented shall be supported by appropriate data that is gathered and recorded in a scientific manner.

17.2.2 Procedure Validation and Validation Records

17.2.2.1 All new/modified procedures must be validated to some extent before, or concurrent with, their first use. At a minimum, any procedure taken directly from reference sources shall be demonstrated to be effective when performed by the Department. Minor modifications of methods already in use shall be evaluated to determine the effects, if any, of the modification. Procedures largely developed at the Department or existing Department procedures which undergo major modifications must be subjected to a formal validation study, in which known samples representative of those encountered in casework shall be examined to determine if the procedure generates acceptable results. If a new procedure will replace, or be an alternative to, an existing method, the new procedure must generate comparable results; this is best done by analyzing split samples using both procedures in parallel. Validation of quantitative analyses must include a determination of the procedure's accuracy and precision over the range of concentrations expected in casework, and also establish the procedure's analytical limits (detection, quantitation and reporting, as appropriate).

17.2.2.2 Validation records that document the acceptability of a new/modified method shall be maintained by the appropriate Section Chief. "Acceptable" results shall be clearly defined in those records. Such records must be available for all new/modified methods used in each Section, including those that may be limited to use in a single laboratory. Any records of studies that are found to demonstrate that a procedure is not suitable for use should also be maintained for potential future reference.

17.2.3 Approval and Implementation of Procedures

17.2.3.1 Procedures shall be available for use after they are formally incorporated into a Section's Technical Procedures Manual (Section 4, "Quality System Manuals and Control").

17.3 Manuals

17.3.1 Each Section Chief is responsible for the generation, maintenance and revision of his/her Section's Technical Procedures Manual. Each Technical Procedures Manual, as addressed in Section 4 of this manual, is a controlled document, and is subject to the Department's document control policies. Each Procedures Manual must describe the procedures used in the Section in sufficient detail to demonstrate, in combination with validation and other applicable records, the procedures' scientific validity. Each Procedures Manual will be available in electronic format on the Department's Intranet. Each Section Chief will ensure that all examiners and technical support personnel in the Section understand the contents of the Procedures Manual.

17.3.2 Each procedure, or related group of procedures, as appropriate, shall be described in a Standard Operating Procedure (SOP). Each SOP will be a section of the Procedures Manual.

17.3.3 The SOP should include the following information, when appropriate:

17.3.3.1 The types of evidence for which the procedure is suitable.

17.3.3.2 The information to be derived from performing the procedure.

17.3.3.3 A summary of the procedure.

17.3.3.4 The equipment and materials needed to perform the procedure, including any specified levels of quality.

17.3.3.5 The procedure should be sufficiently detailed and written in a manner that any examiner or technical support personnel following the written procedure would perform the procedure in essentially the same manner, and would generate the same results. The procedure should include, as necessary:

- Any unique safety warnings
- Sampling protocols to be used when the procedure will be applied to only a portion of the evidence
- Any settings, checks, adjustments or calibrations of equipment and/or materials before use
- Quality control requirements (¶ 17.3.4, below)
- The data, observations and results to be recorded and the method of recording them
- Calculations
- Criteria for acceptance or rejection of data

17.3.4 Each Procedures Manual must also describe, in SOPs when appropriate, quality assurance procedures unique to the Section, and details of how Department QA requirements in this manual are implemented.

17.3.5 QC Practices and Components

Section Chiefs will define quality control (QC) requirements for each of the Section's procedures. As appropriate, the following QC practices and components will be addressed in the Procedures Manuals.

17.3.5.1 Batching - The grouping of evidential and QC samples to associate the results of the examinations of the QC samples with those of the evidential samples.

17.3.5.2 Standards – Materials or items of known or well-established composition used to prepare QC samples or used as QC samples. Standards must be verified and documented (¶ 18.3) prior to use on casework.

17.3.5.3 Calibration – The determination of the relationship between a measurable property of a sample and the response of the measuring instrument or device using calibration standards (calibrators).

17.3.5.4 2nd Source Calibration Check - The assessment of the applicability of a calibration using an "independently prepared" standard immediately after calibration.

17.3.5.5 Calibration Checks – The assessment of the applicability of a calibration over a protracted time period using calibration standards.

17.3.5.6 Blanks (Negative Controls) - QC samples which determine if any contamination is present in all or part of an analytical procedure. Procedures will define the frequency at which negative controls will be run and where results will be recorded.

17.3.5.7 Laboratory Control Samples (Positive Controls) - QC samples which determine if the analytical process has been performed properly/successfully. Procedures will define the frequency at which positive controls will be run and where results will be recorded.

17.3.5.8 Matrix Spikes - QC samples which assess the effect of the sample matrix on the analytical process.

17.3.5.9 Replicates - Evidential or QC samples that determine the precision of the analytical process.

17.3.5.10 Sample QC – The assessment of a result of the analysis of an evidential sample other than that for the analyte of interest, e.g., internal standard recovery.

17.3.5.11 Acceptance Criteria - Results of the analyses of standards, QC samples or evidential samples that allow the reporting of evidential sample results.

17.3.5.12 Statistical Acceptance Criteria – Acceptance criteria developed by statistical analysis of historical or associated data.

17.3.5.13 Documentation – Written records pertaining to QC analyses and results.

- Controls and standards specified in procedures must be used and documented in the case record.
- Written records or logs must be maintained for each piece of equipment, showing calibration results and dates, repair records, and other information appropriate to the instrument.

17.3.5.14 Corrective Actions – Defined responses to analytical results which do not meet acceptance criteria.

17.3.5.15 Explanation of codes and abbreviations used by examiners in recording notes.

17.3.6 Protocol Deviations

It must be noted that many examinations often are not, and cannot, be performed exactly as written in the Department's SOPs because of the widely variable nature of evidence. When such deviations are foreseeable, they should be addressed in the appropriate Procedures Manual or an SOP, as appropriate.

17.3.6.1 As noted in ¶ 13.8.5, examination documentation must record unexpected deviations from written technical procedures occasioned by unusual evidence. In addition, deviations should be discussed with the examiner's supervisor and/or Section Chief. Major deviations shall require formal written approval by the Section Chief.

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